

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: WAVE 4 CASES ON ATTACHED EXHIBIT A</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION  
TO EXCLUDE CERTAIN OPINIONS OF DR. STANLEY ZASLAU**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that the Court exclude certain opinions and testimony of Defendants' Urology and Female Pelvic Medicine and Reconstructive Surgery expert, Stanley Zaslau, M.D., MBA, FACS ("Dr. Zaslau"). In support of their Motion, Plaintiffs state as follows:

**INTRODUCTION**

Dr. Zaslau is board certified in Urology and certified in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery. Exhibit B, Zaslau CV, p. 3. Plaintiffs do not challenge his qualifications as such. However, Dr. Zaslau seeks to offer testimony that is not helpful for the jury, clearly exceeds the bounds of his qualifications, and is founded on insufficient facts and unreliable methodology.<sup>1</sup> Specifically, this Court should exclude Dr. Zaslau's opinions regarding: (1) the adequacy of Defendants' product warnings and IFUs, including opinions regarding what risks of the devices other doctors know of; (2) Whether Defendants' transvaginal mesh products are defectively or reasonably designed; (3) particle loss and fraying of

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<sup>1</sup> See *Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.).

mechanical-cut mesh; (4) roping or curling of mechanical-cut mesh; (5) the degradation of polypropylene or its clinical significance; (6) whether the products at issue are associated with chronic or long term pain; and (7) Any opinion regarding safety, efficacy, or personal satisfaction rates of the mesh products observed in his own practice.

### **LEGAL STANDARD**

Under Rule 702 of the Federal Rules of Evidence, as interpreted by the Supreme Court in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), an expert witness may be qualified by “knowledge, skill, experience, training or education.” Fed. R. Evid. 702. The witness’s testimony also must represent “scientific knowledge,” meaning that it is supported by appropriate validation; and it must assist the jury, meaning that it must be relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) “will help the trier of fact to understand the evidence or to determine a fact in issue,” (2) is “based upon sufficient facts or data,” (3) is “the product of reliable principles and methods” and (4) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. Opinion evidence may be admitted if it “rests on a reliable foundation and is relevant.” *Daubert*, 509 U.S. at 597. In the end, an expert’s testimony is admissible if it “rests on a reliable foundation and is relevant.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The duty rests with Dr. Zaslau to proffer expert testimony and “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Maryland Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). Even if Dr. Zaslau is qualified and his testimony is reliable, “testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.” *In re Ethicon, Inc., Pelvic Repair*

*Sys. Products Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872 (S.D.W. Va. Jan. 15, 2014) *reconsideration denied*, 2014 WL 457544 (S.D.W. Va. Feb. 3, 2014). In other words, his testimony must “fit” the case, and there must be a “valid scientific connection to the pertinent inquiry as a precondition to admissibility. *Id.*

## ARGUMENT

### **1. Dr. Zaslau’s opinions on the adequacy of defendants’ warnings and what other doctors know about the risks of pelvic mesh devices should be precluded pursuant to *Daubert***

Dr. Stanley Zaslau’s testimony is unreliable as he admits his opinions on the adequacy of defendants’ warnings are based on nothing more than personal convictions regarding what risks are commonly known to physicians about the device. Thus, they are *ipse dixit* opinions and precluded under *Daubert*. Dr. Zaslau has no independent knowledge of FDA requirements and no knowledge of industry standards. He admits he performed no independent research at all on standards of any kind before publishing his expert report. Finally, he attempts to shoehorn into evidence the same type of testimony by providing impermissible, speculative testimony regarding what risks he believes “all doctors” knew or did not know about the device, while admitting he has not used any reliable methodology in arriving at that conclusion. Such testimony lies at the heart of what *Daubert* and its progeny have found inadmissible.

This Court is obliged to exercise a “gatekeeping” function to ensure that expert testimony is both relevant and reliable. FED. R. EVID. 702; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (citing *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993)). This obligation applies to all types of expert testimony, not merely scientific analysis. *Kumho Tire*, 526 U.S. at 149; *Holsesapple v. Barrett*, No. 00-1537, 2001 WL 208490, at \*1 (4th Cir. 2001). The proponent of the testimony has the burden of proving both relevance and reliability. *Bickel*

*v. Pfizer, Inc.*, 431 F. Supp. 2d, 918, 921 (N.D. Ind. 2006). While an expert who is a urologist or pelvic floor surgeon may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU. *Wise v. C. R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at \*14 (S.D. W. Va. Feb. 7, 2015). Dr. Zaslau does not possess the additional expertise to offer expert testimony about what an IFU should or should not include, and therefore, his testimony regarding these issues should be excluded.

Dr. Zaslau relies solely on 21 CFR 801.109(c) and his personal convictions regarding what risks are generally known to surgeons for his opinion that the Pelvic mesh IFU's are adequate from a clinical standpoint, as well as a regulatory standpoint. Exhibit C, Zaslau Gynemesh PS and Prolift report, p. 50. However, Dr. Zaslau admits he is not a regulatory expert and did not obtain this CFR section through his own independent research; rather, it was provided by counsel for defendants, and he does not even know what "CFR" means or stands for:

Q. Doctor, earlier defense counsel was asking you about a section of your report regarding the IFU on page 50 where 21 CFR 801.109(c) is cited.

A. Yes.

Q. Is that the only objective standard you're relying on for your opinion regarding the sufficiency of the IFU

[Def. counsel]: object to form.

A. Again, I'm not a regulatory expert, I have looked at that in some detail, and that is my opinion. The manufacturers can omit warning information that would be commonly known to practitioners that are licensed to use the device in his case

Q. What does CFR stand for?

A. CFR, I don't remember. Something – I think R was regulatory. I don't remember what the CF stands for

Q. How did you get that standard? Was that provided to you by counsel?

A. It was, yes, and then I reviewed what that was

Q. So it's not any standard that you encountered on your own through your own independent research?

A: No<sup>2</sup>

Dr. Zaslau is not a regulatory expert.<sup>3</sup> He has never written an IFU.<sup>4</sup> He is not an expert on FDA regulations or device warnings.<sup>5</sup> More troubling is that he has not considered the specifics of any other FDA standards which are contrary to his opinion, such as the blue book standard, which states that an appropriate warning should be included in an IFU if there is reasonable evidence of an association of a serious hazard with the use of a device, regardless of whether a causal relationship has been proven.<sup>6</sup> Dr. Zaslau appears to have relied solely on a single section of the Code of Federal Regulations fed to him by counsel for Defendants for his opinions that the Pelvic Mesh (Prolift) IFU's are adequate. In addition, he admits that he does not have the regulatory or legal background required to interpret such a standard.

Dr. Zaslau gives the opinion that the Prolift IFU created in 2005 were adequate to warn physicians regarding the risks of the product.<sup>7</sup> His opinion is based on his contention that 21 CFR 801.109(c) allows manufacturers to omit warnings that would be commonly known to physicians using his device, coupled with his speculative, unsupported opinions regarding what risks other physicians knew about the device. Moreover, Dr. Zaslau could not offer an opinion

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<sup>2</sup> Dr. Zaslau Dep. Tr., 03-08-2017, 204:13-205:15; Plaintiff's Motion, Exhibit D.

<sup>3</sup> *Id.* at 146:5-9

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 204:17-21

<sup>6</sup> *Id.* at 205:14-14-20; Compare with Ex. E, Blue Book Memo, Section V. (page 4/10)

<sup>7</sup> *Id.* at 145:8-23.

regarding whether the Prolift IFU at launch—which did not include a warning regarding pain and dyspareunia as a potential adverse event—was more or less appropriate than the subsequent IFU:

Q. Which do you think is the more appropriate Prolift IFU, the one that includes dyspareunia and pain as a potential adverse event, or the one that doesn't?

A. Which is more –

Q. Which is more appropriate?

A. **Which is more appropriate? I don't have an opinion as to either of them.** I think the one that has it is more complete, but the initial one is certainly appropriate because any pelvic surgeon knows that. These are risks of pelvic floor surgery. That is well-known and well described.<sup>8</sup>

Dr. Zaslau states repeatedly in his report that the risks of the pelvic mesh devices are well-known to physicians,<sup>9</sup> and uses this as part of the basis for his opinion that the IFU's are adequate. However, Dr. Zaslau has never done any kind of survey or used any kind of formal methodology to determine what physicians did or did not know with regard to the pelvic mesh devices.<sup>10</sup> He has never done any kind of formal analysis to determine what percentage of mesh users knew or did not know that, for example, pain or chronic pain was a potential risk of the pelvic mesh devices, or what percentage of physicians using the mesh devices knew of the risk of chronic dyspareunia<sup>11</sup> Since Dr. Zaslau is relying on what physicians commonly knew about the risks of the devices as a component of his opinion that the IFUs were adequate—yet he cannot state what percentage of physicians knew about particular risks—then he cannot testify reliably as to whether the IFUs were adequate. He admits his opinion is not grounded on any objective evidence. Rather Dr. Zaslau simply provides his own *ipse dixit* to support his opinions.

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<sup>8</sup> *Id.* at 151:19-152:7 (Emphasis added)

<sup>9</sup> *Id.* at 152:8-11

<sup>10</sup> *Id.* at 152:19-4

<sup>11</sup> *Id.* at 153:12-23, 154:19-154:11

Further, While Dr. Zaslau has stated his intention to opine that the original Prolift IFU issued in 2005 was at all times adequate, he has stated that he does not intend to offer an opinion that the warnings in the Gynemesh PS IFU are adequate.<sup>12</sup> This is curious, given that the Prolift device is made from the Gynemesh PS mesh,<sup>13</sup> and the adverse reactions section of the IFU for the Gynemesh PS device underwent a substantial update to the adverse in 2015—adding, among other things, the risks urge continence, urinary frequency, chronic pain, excessive contraction or shrinkage of the tissue surrounding the mesh, pelvic pain which may not resolve, pain with intercourse which may not resolve, and neuromuscular problems, including acute, and or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area.<sup>14</sup> None of these risks added to the Gynemesh PS IFU in 2015 ever appeared in the Prolift IFU.<sup>15</sup> Dr. Zaslau’s unwillingness to offer an opinion that the IFU for the underlying mesh material used in the Prolift is adequate is at odds with his opinion that the Prolift IFU was at all times adequate, as is his lack of an opinion regarding whether a Prolift IFU that includes a warning for dyspareunia and pain is more appropriate than one which omits that warning.<sup>16</sup>

Dr. Zaslau’s opinions that physicians knew of all the risks of the pelvic mesh devices appears to be based on his personal conviction that any doctor who reads a core textbook in urology or gynecology knows of the risks of complications from the pelvic mesh, including dyspareunia and pain.<sup>17</sup> However, he has no objective evidence for this conclusion, and it is purely speculation as he has conducted no inquiry into what risks doctors who use the pelvic mesh devices actually know. Dr. Zaslau’s testimony on the adequacy of Defendants’ warnings

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<sup>12</sup> *Id.* at 145:8-23. Compare with 184:7-17

<sup>13</sup> Prolift +M Clinical Expert Report, page 5, Plaintiff’s Motion, Exhibit F

<sup>14</sup> Exhibit G, 2010 Gynemesh PS IFU, compare with Exhibit H, 2015 Gynemesh PS IFU

<sup>15</sup> Exhibit I, 2010 to present Prolift IFU.

<sup>16</sup> *Id.* at 151:19-152:7

<sup>17</sup> *Id.* at 153:12-23

should be excluded because it is based on no objective criteria, but instead, on Dr. Zaslau's personal belief that all surgeons have reviewed and retained information in certain textbooks and other materials. Federal courts have consistently held that *ipse dixit* opinions are inadmissible. *See, e.g., GE v. Joiner*, 522 U.S. 136, 146 (1997); *see also Pampered Chef v. Alexanian*, 804 F. Supp. 2d 765, 794 (N.D. Ill. 2011) ("If admissibility could be established merely by the *ipse dixit* of an admittedly qualified expert, the reliability prong would be, for all practical purposes, subsumed by the qualification prong."). This Court has also excluded *ipse dixit* opinions. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 603 (S.D.W. Va. 2013).

To be admissible, expert testimony must explain the link between the available evidence or data and the expert's opinion. *United States v. Mamah*, 332 F.3d 475, 478 (7th Cir. 2001); *see also Cunningham v. Masterwear, Inc.*, No. 1:04-cv-1616-JDT-WTL, 2007 WL 1164832, at \*9 (S.D. Ind. Apr. 19, 2007) ("It is not enough for an expert to say this is my data and that is my conclusion without connecting the two."); *Mid-State Fertilizer Co. v. Exchange Nat. Bank of Chicago*, 877 F.2d 1333, 1390 (7th Cir. 1989) ("An opinion has a significance proportioned to the sources that sustain it.").

Similarly, in this case, Dr. Zaslau's testimony on the product warnings, by his own admission, is based on a single section of the Code of Federal Regulations given to him by counsel for defendants which is not qualified to interpret, and his unsupported *ipse dixit* testimony that all physicians already know of the risks of the pelvic mesh devices. Those opinions are thus inadmissible under the *Daubert* line of cases.

**II. Dr. Zaslau should be precluded from giving opinions on the design of the mesh products, including whether the devices are designed in a reasonable manner.**

Dr. Zaslau should be precluded from offering any opinions regarding the design of the subject products. Specifically, he should be precluded from offering any opinions regarding whether or not the subject products are defectively designed, whether a mesh device design without mesh arms is more safe or effective than a mesh device which does not utilize mesh arms, any testimony regarding the effect of trocar passes on the safety of a device, and opinions regarding mesh design, and from offering any opinions regarding the sufficiency of the defendants' risk assessments performed during the design of the products, including but not limited to the design failure modes effects analysis (dFMEA), process failure modes effects analysis

The most compelling reason why Dr. Zaslau should be precluded from opining about the design of the subject products is that he admits he is not an expert on design of the mesh products, including the Prolift, the Gynemesh PS, or mesh design in general:

Q. Am I correct that you don't hold yourself out as an expert with regard to the design of Medical device kits for the treatment of prolapse

A. No, I am not an expert.

Q. Am I correct that I wouldn't expect you to offer any opinions with regard to the design of the Prolift?

A. No.

Q. I'm not correct or I am correct?

A. You are correct.

Q. Same question with regard to the Gynemesh PS.

A. Correct, I have no opinions on design

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Q. Am I correct that you don't hold yourself out to be an expert with regard to the type of mesh used in the Prolift?

A. Other than knowing its basic characteristics and the type one macropore filaments, no.<sup>18</sup>

This Court has previously recognized the importance of an expert's admission that he is not an expert. In the *Bard* litigation, this Court precluded Dr. Shull from giving warnings opinions because he had testified that "I would not claim to be an expert in that area." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D.W. Va. 2013), *amended on reconsideration in part* (June 14, 2013). That same analysis applies here to Dr. Zaslau who admitted he is not an expert on design of the mesh products or the mesh itself. As such, he should be precluded from giving any opinions related to design of the subject products, including whether or not the products are designed in a reasonable manner.

**a. Dr. Zaslau did not review Defendants' key documents related to product design, and has not done any analysis of the safety of the design of the products as it relates to the use of mesh arms and trocar passes in the design of the devices.**

Dr. Zaslau should also be precluded from opining about the design of the subject products because he has not reviewed Defendants' internal documents about the design process. This issue was central to the exclusion of design opinions by a urogynecologist for the plaintiffs in the Boston Scientific litigation. Boston Scientific Corp. ("BSC") moved to exclude Dr. Bob Shull because he "reached opinions on the improper design of the Uphold without having first considered BSC's design protocols." *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at \*14 (S.D. W. Va. Apr. 24, 2015). The plaintiffs countered that Dr. Shull had relied on other BSC internal documents, as well as the scientific literature. *Id.*

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<sup>18</sup> Dr. Zaslau Dep. Tr., 03-08-2017, 133:2-13, 134:1-5. Plaintiff's Motion, Exhibit D.

This Court agreed with BSC and excluded Dr. Shull from giving any design opinions. This Court reasoned that “regardless of the literature he has reviewed or the experience he has gained, a necessary piece of data remains missing from Dr. Shull’s methodology. Without any reliable, demonstrated knowledge of BSC’s internal design procedures, Dr. Shull cannot substantiate his opinion that these procedures were (1) departures from the norm; (2) not followed by BSC; or (3) lacking in any way.” *Id.*

Dr. Zaslau also confirmed he has not read the design failure modes and effects analysis for the subject products, and does not know what that phrase means.<sup>19</sup> He admits he has no opinion as to whether a product with mesh arms is more or less likely to cause complications than a product without arms like the Prolift, and has done no analysis of whether a mesh product without arms like the Prosima is superior to a product with mesh arms like the Prolift.<sup>20</sup> He also admits it would be “hard to say” whether a mesh product for the repair of pelvic organ prolapse which has zero trocar passes is more or less likely to cause complications than a product like the Prolift that has multiple trocar passes, and does not know if when designing a product or procedure, you would want to design it with as few trocar passes as possible.<sup>21</sup> Further, Dr. Zaslau does not even know whether or not the Gynemesh PS mesh (which is also used in the Prolift) is currently indicated for transvaginal use or not.<sup>22</sup>

Dr. Zaslau did not review the relevant design documents, and has not done the appropriate analysis with regard to the use of mesh arms and trocars in a mesh product, or the indications for use for the Gynemesh PS and Prolift mesh. Thus, Dr. Zaslau lacks the required

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<sup>19</sup> Ex. D at 133:14-17; 133:21-24.

<sup>20</sup> *Id.* at 43:10-14, 42:11-18.

<sup>21</sup> *Id.* at 44:9-18, 46:4-16.

<sup>22</sup> The indications for use for the Gynemesh PS mesh (also used in the Prolift) have been changed from having an indication for transvaginal placement, to being indicated for abdominal use only. See indications for use section, Exhibit G, 2010 Gynemesh PS IFU, compare with Exhibit H, 2015 Gynemesh PS IFU. This is a key design change as the mesh is no longer “designed” for transvaginal placement

knowledge and foundation to give a reliable opinion about the design and reasonableness of Defendants' transvaginal mesh products, including but not limited to the reasonableness of designing the Gynemesh PS and Prolift for transvaginal placement, and the reasonableness of designing a mesh product with trocars and mesh arms. Based on the foregoing, all Dr. Zaslau opinions on the issue of product design should be excluded.

**III. Dr. Zaslau's opinion that particle loss or fraying does not occur with mechanical-cut mesh, or that it has no clinical significance, is not reliable**

Dr. Zaslau seeks to testify that he has "not removed degraded particles of mesh or seen grossly altered structure of the knitting of the mesh" in the specimens that he has explanted. (Zaslau TVT and TVT-O Report p. 72, Ex J). The underlying logic of Dr. Zaslau's opinion regarding (the absence of) particle loss and mesh fraying in mechanical-cut mesh is essentially: 'I have not seen it, so it does not happen.' Dr. Zaslau admits that he did not know the difference between mechanical-cut and laser-cut mesh until taking part in this litigation, and that his opinion is wholly-based upon his proclamation that he has not noticed a difference between the two types of mesh in his personal experience:

Q. And how do you know whether or not you're using a mechanical-cut versus a laser-cut mesh?

A. Well, I actually didn't know the difference until these litigation cases have brought this into the world. I've had no issues with -- in knowing the difference in either of them, nor do I think it has any clinical relevance.

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Q. Well, Ethicon felt that there was a clinical need for a laser-cut mesh, didn't it?

A. I don't know that they -- I know that they have -- that information had been given to them, that, you know, maybe this should be considered, and obviously they did. But it wouldn't have mattered to me. I've not seen a difference or a need for it.

Exhibit K, Zaslau 3/2/16 Dep., 99:1-24.

That is simply not a reliable basis for a biomedical opinion regarding the particle loss or fraying found in mechanical-cut mesh. This Court has previously rejected this sort of "I have not

seen it, therefore it must not happen” logic. Indeed, in ruling on *Daubert* motions in *Tyree*, the Court held that the “[a]bsence of evidence is not evidence of absence,” and refused to allow defendant’s expert to opine that certain events do not occur simply because he had not observed them in his practice.<sup>23</sup> By that same unassailable reasoning, Dr. Zaslau’s claim that, *as far as he knows*, the mesh he has explanted did not experience particle loss of fraying cannot serve as a reliable scientific basis for rendering the opinion that it did not occur. Therefore, this unscientific testimony should be excluded.

Moreover, Dr. Zaslau admits that his opinion is contradicted by the scientific literature and Ethicon’s own internal documents—but to that fact, he simply responds that his opinion “differs,” that even if particle loss does occur it must have no “clinical significance,” and that he has “no other comments”:

Q. And have you ever been told that the TVT mechanical-cut mesh can release -- that there can be particle loss associated with the mechanical-cut mesh?

A. I’ve read that.

Q. And my understanding is you don’t believe that has clinical significance?

A. I don’t think it does.

Q. You would agree with me that you’ve seen reports of that in the literature?

A. Yes.

Q. And you would agree with me, given your hefty reliance list, that you’ve also seen some Ethicon documents on that?

A. Yes.

Q. And you still conclude, even after reviewing those documents and that literature, that there is no clinical relevance to that issue?

A. That’s correct.

Q. And you would agree with me that the particle loss that Ethicon describes, as well as the literature, is from the TVT mesh itself –

Q. -- which is a foreign body?

A. That the particle loss is from the TVT?

Q. Correct. It’s pretty well-accepted, right?

A. Yeah.

Q. I’m not trying to start a disagreement between us. I’m just trying to get through this. And you would agree with me that your opinion differs from other physicians about the clinical relevance of particle loss?

A. **It differs.**

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<sup>23</sup> *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 583-85 (S.D. W. Va. 2014)).

Q. In what way?

A. Well, experts believe that this can be a source of pain for patients, and other associated symptoms that are supposedly debilitating and lifelong and very problematic.

Q. And you would agree with me that Ethicon itself concluded, at least in part, that the clinical basis for coming up with the laser-cut mesh was the particle loss associated with the mechanical-cut mesh?

A. That may have been a consideration for them, but --

Q. In fact, you've seen documents that suggest that?

A. Yeah.

Q. And your reliance list. Even you've seen Ethicon documents that suggest that's a clinical basis for changing the laser-cut mesh, right?

A. It very well could be.

Q. I mean, you're not going to disagree with a document that you've seen that says that, right?

Q. Correct?

**A. I have no other comments.**

Ex. K, 104:3-10; 105:3-106:5.

Dr. Zaslau went on to testify that his opinion could not be changed even if he was shown documents establishing the significance of particle loss, and that—based solely on his personal observations—he does not “need to consider” contradictory scientific evidence:

Q. Well, look at the middle of the page. It says, “Particle loss is the reason why TVT wants to use laser-cut mesh to eliminate particle loss (which is critical to quality).” Do you see that?

A. I do.

Q. Do you agree with that statement?

A. I've not seen that as an issue, okay? I've also looked at mesh as it comes out of the package from the very beginning. I've not seen any – even any threads that are lost off of any mesh over the years as we take it out and check its expiration date and other opinion of it. So to me, I don't see any difference between laser-cut and mechanical-cut mesh.

Q. Have you seen any studies that conclude otherwise?

A. No.

Q. You haven't?

A. No.

Q. Have you seen any documents where the – one of the co-inventors of the TVT product believes that they won't use laser-cut mesh?

A. No.

Q. You haven't seen that?

A. No.

Q. Wouldn't that affect your opinion?

A. No.

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Q. So -- okay. So fair enough. You just don't consider Ethicon documents in that regard one way or another to support your opinion?

A. These have no effect on my opinion whatsoever.

Q. And you're just -- in other words, you just, because of your own experience, you're just not going to consider them?

A. I don't have -- no.

**A. I don't need to consider them.**

Ex. K. 137:5-138:8; 140:3.

As this Court held in *Sanchez*: “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’ ‘[I]f the relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.’”<sup>24</sup>

Moreover, this type of “no it’s not” *ipse dixit* testimony is not helpful to the jury—because it provides no scientific basis upon which the jury could rely.<sup>25</sup> Neither *Daubert* nor the Federal Rules of Evidence require the admission of opinion evidence that is merely *ipse dixit* of the expert, and a court may conclude that there is too large of an analytical gap between the data and the opinion proffered.<sup>26</sup> That is precisely the case here.

**IV. Dr. Zaslau’s opinion that mechanical-cut mesh does not rope or curl—so long as it is implanted using the accompanying sheath—is equally unreliable**

Similar to his opinion regarding particle loss, Dr. Zaslau’s opinion that mechanical-cut mesh will not rope or curl when properly implanted using the accompanying plastic sheath is based solely on his own observations, which are admittedly contradicted by the scientific

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<sup>24</sup> *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 U.S. Dist. LEXIS 137189, \*70 (S.D. W. Va. Sept. 29, 2014) (citations omitted).

<sup>25</sup> *Ipse dixit* is defined as “[h]e himself said it; a bare, assertion resting on the authority of an individual.” See Black’s Law Dictionary 828 (6th ed. 1990); see also *Sadow-Pajewski v. Busch Entertainment Corp.*, 55 F. Supp. 2d 422, 427 (E.D.Va. 1999).

<sup>26</sup> *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

evidence. And when asked for support for his observations, Dr. Zaslau said that we would just have to “take his word for it”:

Q. Has anyone ever told you that the TVT mechanical-cut mesh can rope?

A. Yes, I’ve heard that.

Q. From who?

A. From review of the literature.

Q. Have you ever observed that?

A. Yes.

Q. When?

A. When we do different experiments with the mesh ex vivo. So when we pull on the mesh by itself, be it mechanically-cut or laser-cut, it’ll rip and tear, and it won’t regain its normal form. And the pore size will certainly be distorted. But, interestingly, when we do the same thing with the plastic sheath over it, we can’t move the mesh despite how hard we pull. We’ve actually even looked with an operative telescope at patients that we finished doing the TVT on to see if there any evidence of fiber loss or any change in what I think the mesh should look like, and I’ve never seen any.

Q. Have you published the results of that testing?

A. We did not.

Q. Where’s the data to back up that claim?

A. It’s personal experience and just bedside teaching.

Q. So I just have to take your word for it?

A. That’s correct.

Ex. K, 102:1-103:5.

Dr. Zaslau’s opinion on whether mesh ropes or curls is nothing more than the same sort of inadmissible “I have not seen it” testimony that he offers regarding particle loss.<sup>27</sup> He admits that his observations cannot be confirmed, and his opinion cannot be contradicted or tested. It is the sort of opinion that *Daubert* was intended to preclude.

**V. Dr. Zaslau should be precluded from testifying that polypropylene does not degrade *in vivo***

Dr. Zaslau seeks to offer the opinion that he has not removed “degraded particles of mesh” (Ex. B, p. 9), and that he does not “believe that [polypropylene mesh] can have any

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<sup>27</sup> *Tyree*, 54 F. Supp. 3d at 583-85.

significant degradation” or that degradation has any “clinical relevance.” Ex. K, 125:15-126:14. Dr. Zaslau’s opinions regarding the degradation of polypropylene mesh should be excluded.

As an initial matter, Dr. Zaslau’s lack of knowledge about the degradation process, and the chemical properties of Prolene, should serve to preclude his so called “expert” opinions on the issue. For example, Dr. Zaslau could not definitively explain the degradation process from a chemical prospective—and admitted that his opinion is contradicted by the peer reviewed scientific literature. Ex. K, 130:20-131:19. Likewise, Dr. Zaslau does not know what additives are used in the manufacture of the polypropylene used to make Prolene mesh. Ex. K, 128:23-129:1.

Moreover, Dr. Zaslau did not review necessary and relevant documents regarding degradation—including Ethicon’s own internal documents—and instead, he just insists that polypropylene mesh does not degrade:

Q. Have you seen any documents concluding that mesh degrades?

A. No.

Q. So you haven’t seen any internal Ethicon documents indicating that mesh degrades?

A. No.

Q. Did you ask for any?

A. No.

Q. Why not?

A. **Because it doesn’t degrade.**

Q. So you disagree with Ethicon?

A. I do.

Ex. K, 124:16-125:3; *see also* 126:15-24; 127:21-24. Dr. Zaslau chooses to ignore the relevant evidence,<sup>28</sup> and instead, just blindly asserts that if degradation was clinically significant, Ethicon would have let physicians know. Ex. K, 160:20-23 (“I know that if there were anything pertinent, internally, regarding this procedure that Ethicon would have let physicians know

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<sup>28</sup> *See Sanchez*, 2014 U.S. Dist. LEXIS 137189, \*70.

immediately.”). However, an expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation.<sup>29</sup>

Dr. Zaslau also testified that he does not test the mesh he explants from patients, so any claim that his degradation opinion is based upon personal experience should be rejected as scientifically unsound. Ex. K, 96:22-97:2, see also, Ex. D, 114:14-22. Similar to the opinions discussed above, Dr. Zaslau’s opinion that degradation does not occur, or that if it does it is not “clinically relevant,” should be excluded because it is neither supported by his review and understanding of the scientific material, nor is it based upon scientifically reliable clinical experience

**VI. Dr. Zaslau’s opinion that the TVT is not associated with chronic or long term pain is completely unsupported, and therefore, unreliable**

Dr. Zaslau testified that “[v]ery few people who have had a carefully-implanted device will have *long-term* pain.” Ex. K, 72:10-12. But when asked to provide *any* support in the scientific literature for that opinion, Dr. Zaslau could not do so:

Q. Okay. But I didn’t ask about erosions or extrusions. I asked you to name one study that tracked chronic long-term pain associated with the TVT.

A. I can’t name one.

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THE WITNESS: I can’t think of or see one that specifically refers to that for the long-term.

Ex. K, 72:22-73:20; *see also* 74:5-75:19. Again, Dr. Zaslau’s opinions amount to nothing more than the type of “unsupported speculation” that must be excluded under *Daubert*.<sup>30</sup>

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<sup>29</sup> *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, \*3 (4th Cir., Sept. 8, 1997); *see also* *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

<sup>30</sup> *Brown*, 1997 U.S. App. LEXIS 23559 at \*3 (the expert’s testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also* *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).

**VII. Dr. Zaslau's opinion about his personal experience related to the safety and efficacy of the pelvic mesh products should be excluded because they are not based on any objective standard, and his analysis and methodology are flawed**

Dr. Zaslau should be precluded from testifying about his perceived safety, efficacy, and patient satisfactions rates with the subject products from his practice, as those opinions are entirely unsupported by any reliable methodology, nor have they been subject to peer review. This court has already ruled that an expert cannot relate precise statistics based on their own assurances that those statistics are reliable. *In re Ethicon*, 2016 WL 4542054 (S.D. W. Va. 2016).

Dr. Zaslau has stated in his deposition that he intends to offer an opinion in his own patients who have been implanted with the Prolift device that his patients have been satisfied and have not had any significant adverse events.<sup>31</sup> However, in arriving at this opinion, Dr. Zaslau admits he has not done any kind of survey regarding the patient satisfaction of these Prolift patients, does not know how many of these patients have been lost to follow-up, does not know how many patients have had an annual follow-up, and has not done any kind of formal analysis of what the average follow-up is for his Prolift patients.<sup>32</sup>

Dr. Zaslau's opinions about patient satisfaction and adverse event rates among his own patients is inappropriate, unsupported, and inadmissible, and are exactly the kind of foundationless testimony this court has excluded in the past. He lacks any reliable methodology or analysis to support his conclusions. In addition, allowing Dr. Zaslau to offer an opinion as to his patient satisfaction rate and "significant adverse event rate" for his own patients would be confusing and misleading to a jury when considering the question of whether or not the mesh

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<sup>31</sup> Ex. D at 116:8-13

<sup>32</sup> *Id.* at 116:19-117:3; 117:15-18; 118:6-9, 201:7-14

devices in question are defective, and should be excluded under Rule 403. Because there is no foundation for his opinions, Dr. Zaslau should be prohibited from providing this testimony.

### **CONCLUSION**

Ethicon, as the proponent of the expert testimony, bears the burden of establishing that Dr. Zaslau is sufficiently qualified and that the proposed testimony satisfies the applicable evidentiary standards for the admission of expert testimony. Considering the lack of experience, knowledge, and reliability inherent in the opinions discussed above, Ethicon cannot carry this burden and his testimony should be accordingly limited.

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 13, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/Thomas P. Cartmell